Optimizing Laboratory Testing Services for Improved Patient Care

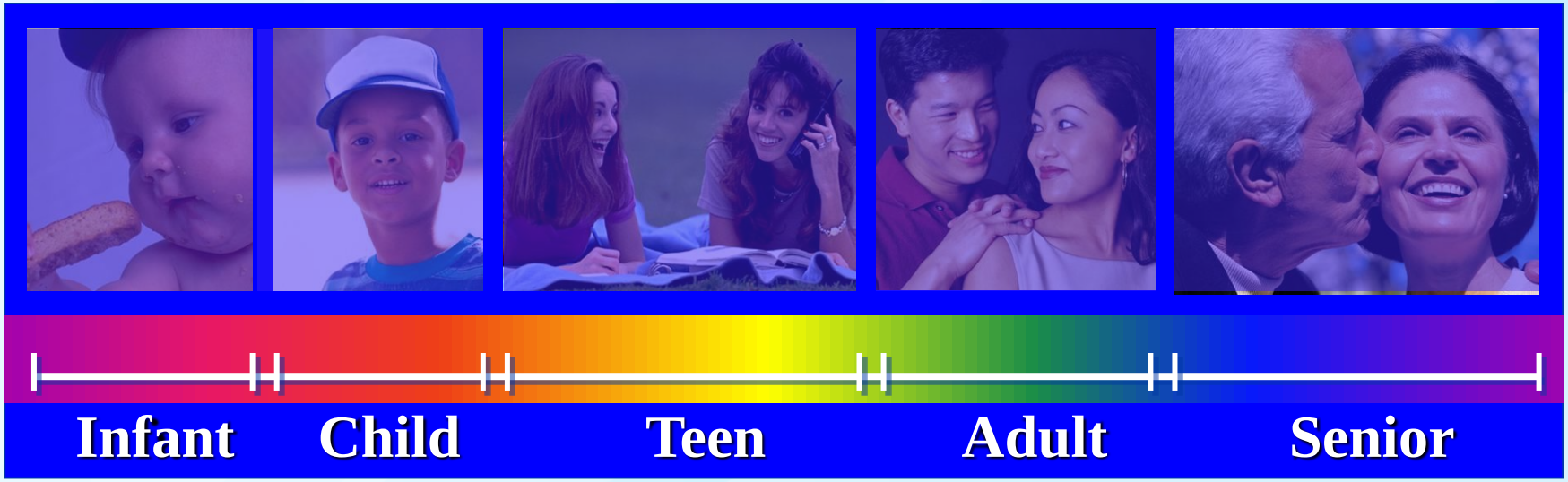
Julie R. Taylor, Ph.D.

COLA Spring 2011 Symposium

27-30 April 2011

Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy, and Practice Program Office

Nearly Everybody's Had a Laboratory Test



Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)™

- History
- Team Members
- Goals and Objectives
- Key Projects

CLIHC™ History

- CDC's Division of Laboratory Systems hosted 6 Institutes
  - – latest in 2007
- Integration Workgroup initiated in 2008 to address some recommendations from institutes
- Focus on optimizing the utilization of laboratory services for better patient care
- Renamed in 2010 –

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)™

CLIHC™ Workgroup

- **Co-Lead: John Hickner, MD, MSc**
  Cleveland Clinic
- **Co-Lead: Michael Laposata, MD, PhD**
  Vanderbilt University Hospital
- **Scott Endsley MD, MSc**
  Cleveland Clinic
- **Paul Epner, MEd, MBA**
  Paul Epner, LLC
- **Marisa B. Marques, MD**
  University of Alabama at Birmingham
- **Jim L. Meisel, MD, FACP**
  Boston Medical Center
- **Elissa Passiment, EdM**
  American Society for Clinical Laboratory Science
- **Brian Smith, MD**
  Yale School of Medicine

Left to Right: Mike Laposata, Elissa Passiment, Paul Epner, Marisa Marques, Bob Hoffman, John Hickner, Brian Jackson, Brian Smith
Not Photographed: Scott Endsley and Jim Meisel

CLIHC™ Workgroup Support

Altarum:

- Kim Bellis
- Beth Costello
- Brian Jackson (ARUP)
- Jim Lee
- Dana Loughrey
- Megan Shaheen
- Tom Wilkinson

CDC:

- Diane Bosse
- MariBeth Gagnon
- James Peterson
- Anne Pollock
- Julie Taylor
- Pam Thompson

Others Participating in CLIHC™ Projects

Samir Aleryani, PhD
Vanderbilt University Medical Center

Julian Barth, MD
University of Leeds, United Kingdom

Allison Floyd, MD
Vanderbilt University Medical Center

John Fontanesi, PhD
University of California at San Diego

George A. Fritsma, MS MT (ASCP)
University of Alabama at Birmingham

John A. Gerlach, PhD
Michigan State University

Robert D. Hoffman, MD, PhD
Vanderbilt University Medical Center

Katherine Kahn, MD
Rand Corporation and UCLA

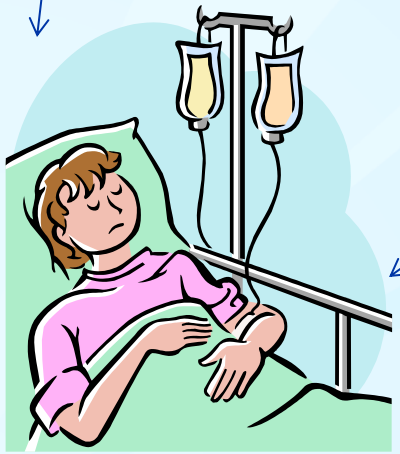
Mario Plebani, MD
University of Padua, Italy

Mitch Scott, PhD
Washington University

Oxana Tcherniantchouk, MD
Cedars-Sinai Medical Center

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)™

Programs and training courses



Systems

Models

Test Selection
Result Interpretation

CLIHC™

- Key Projects
  - Clinician Test Selection & Result Interpretation
    - Diagnostic Algorithms
    - Nomenclature
    - Survey of Clinicians' Challenges
    - Improvement in Test Selection and Result Interpretation (ITSRI)
  - Medical Student Education
    - Survey of US Medical Schools
    - Clinical Pathology Residency Education
  - Develop Organizational Collaborations

Clinician Test Selection and Result Interpretation

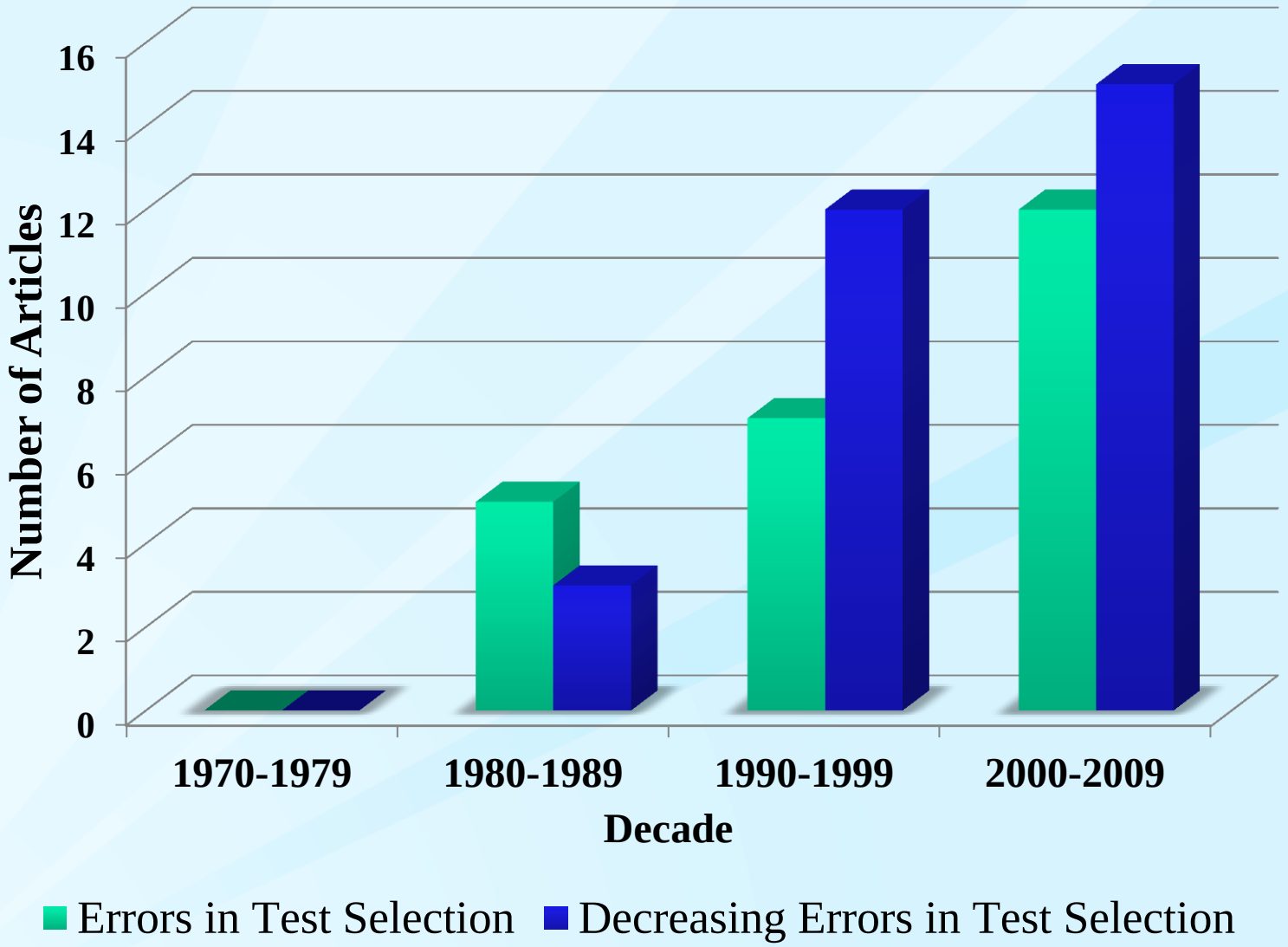
A 40-year review of the literature

Revealed

An increasing number of reports showing that errors in test selection and result interpretation jeopardize patient safety

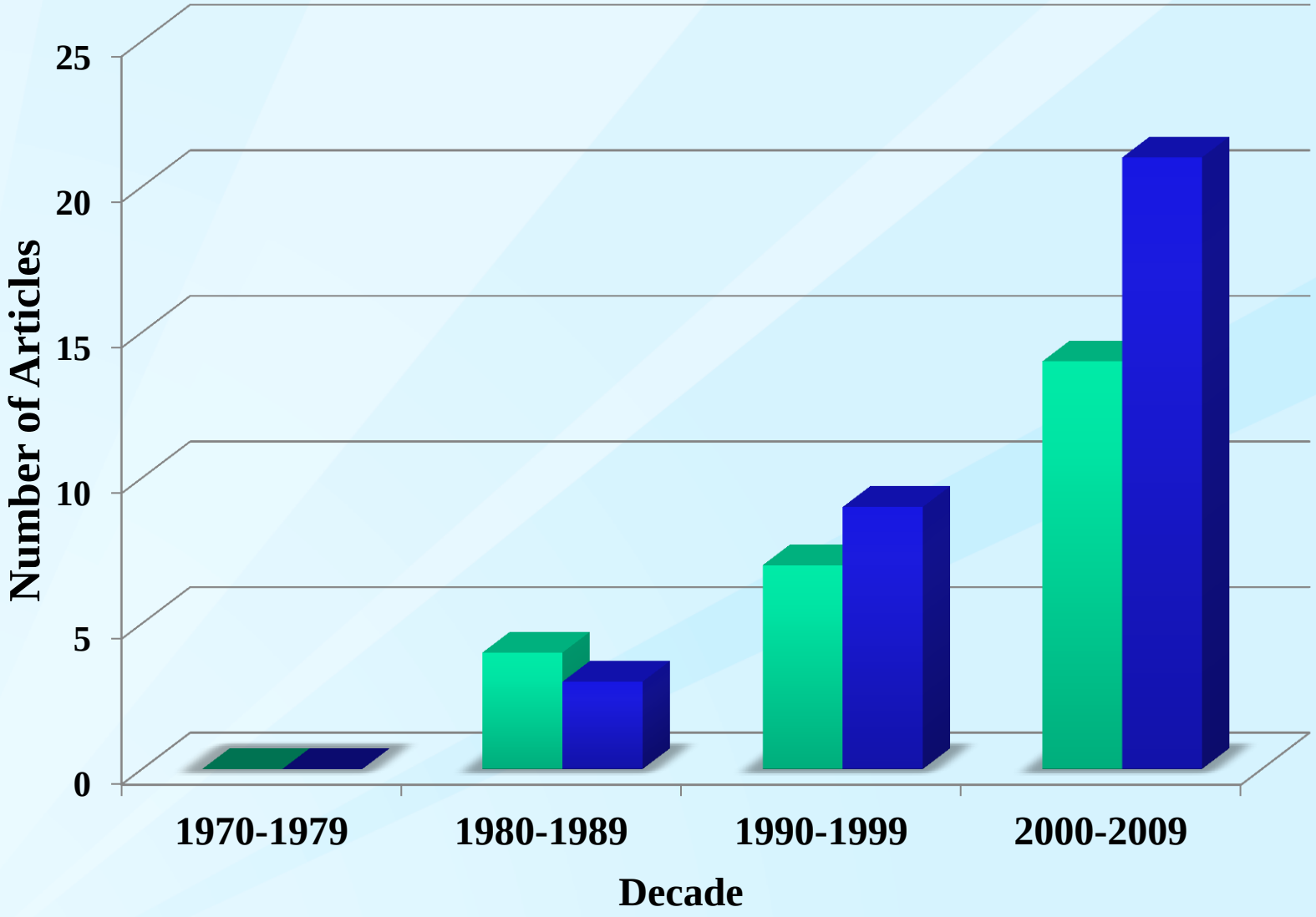
Allison Floyd, MD and Michael Laposata, MD, PhD,
Vanderbilt University Medical Center, unpublished data

Articles on Test Selection Errors



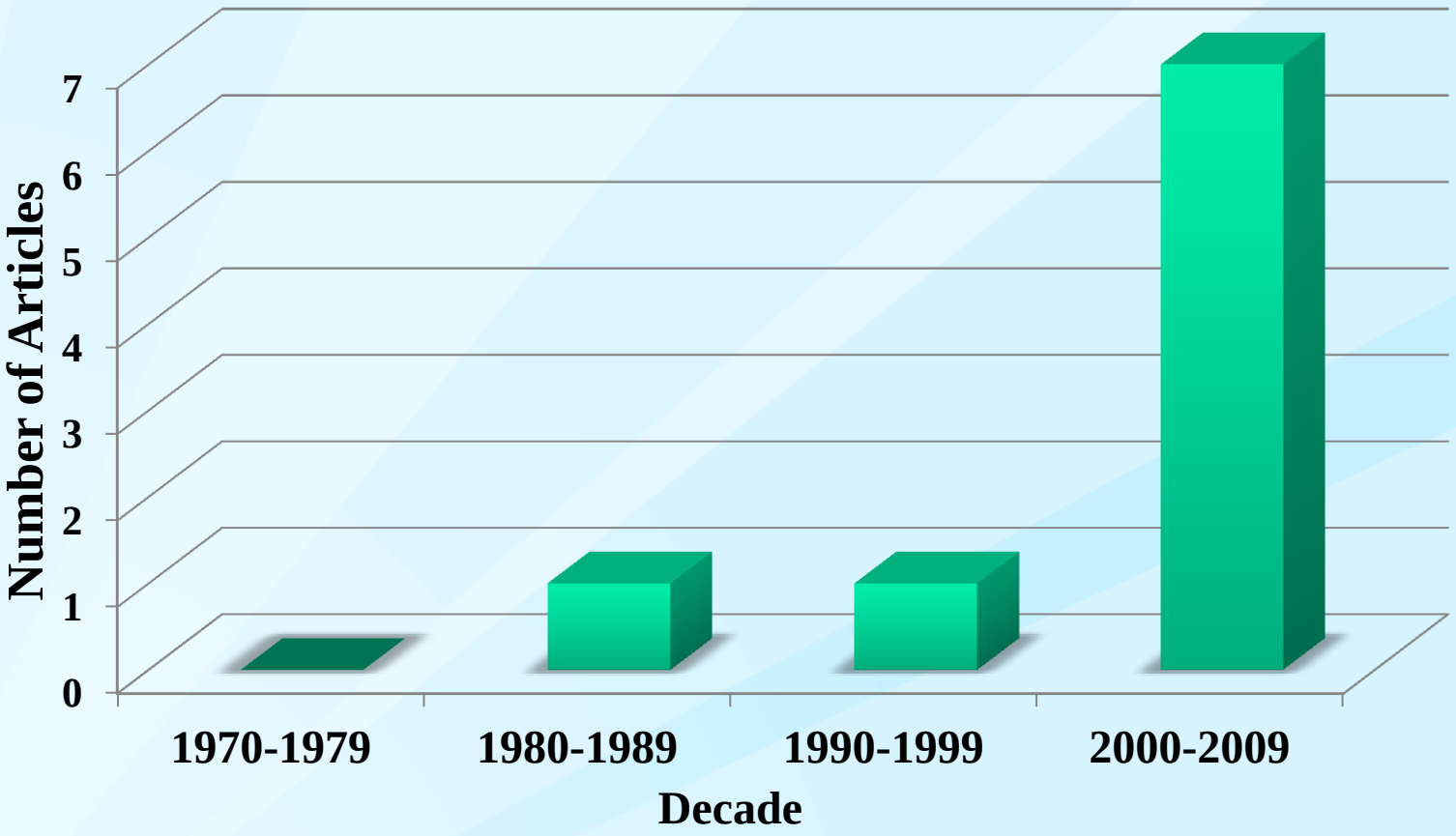
Allison Floyd, MD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center, unpublished data

Articles on Result Interpretation Errors

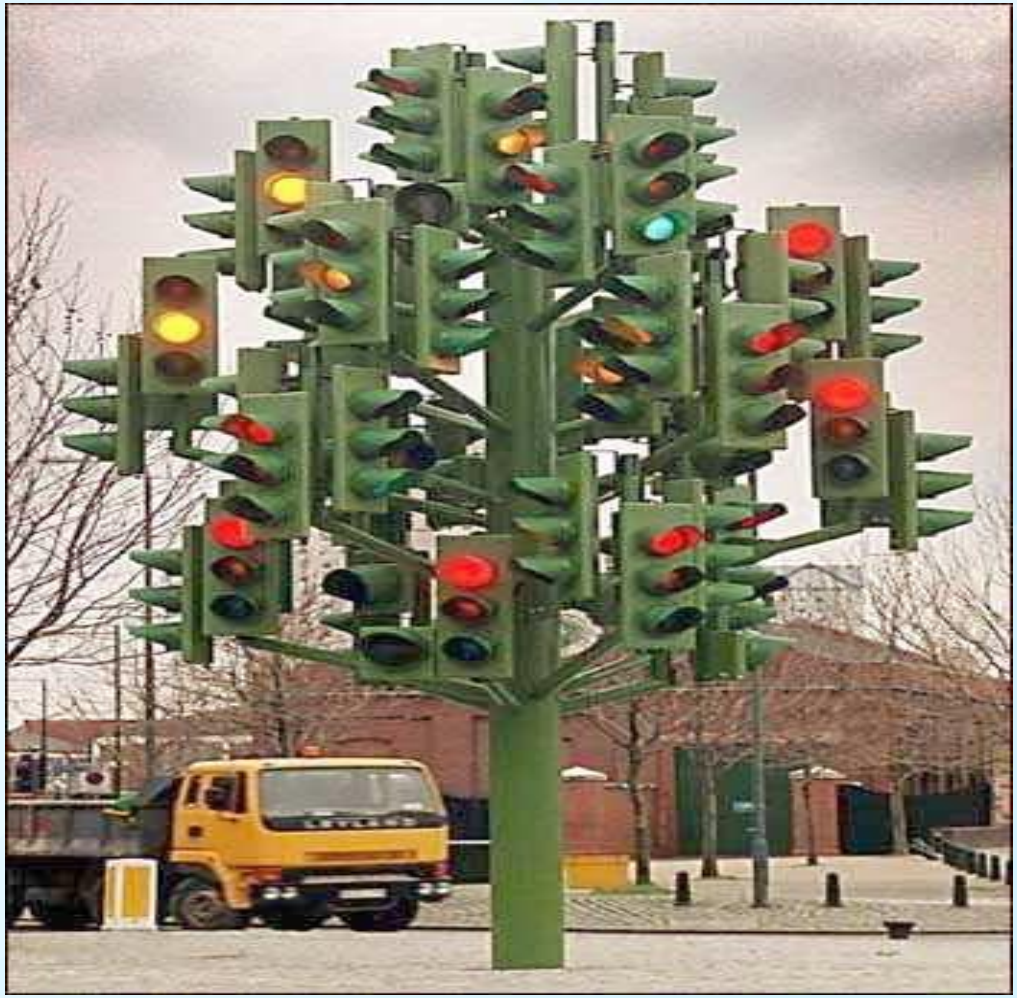


Allison Floyd, MD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center, unpublished data

Articles on Adverse Outcomes



Allison Floyd, MD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center, unpublished data

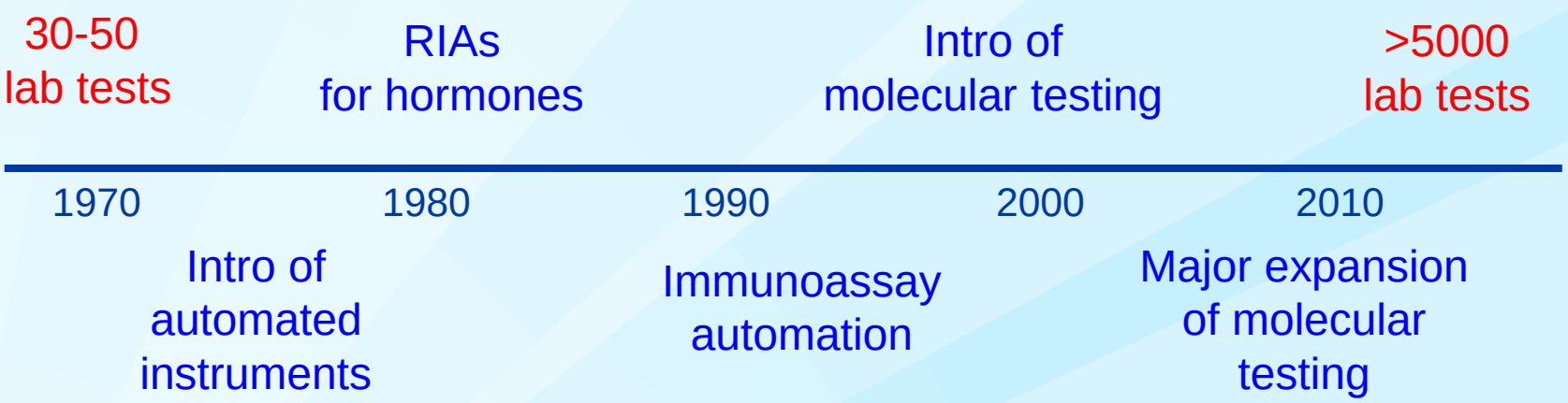


Clinical Laboratory Testing - 1970

30-50
lab tests

Michael Laposata, AACC 2010

Clinical Laboratory Testing - Today



Michael Laposata, AACC 2010

Diagnostic Algorithms

Project Leads – Michael Laposata, MD, PhD and Marisa B. Marques, MD

Goal:

- Demonstrate complexity of selecting the appropriate laboratory test
- Understand the most effective testing strategies

Diagnostic Algorithms

Project Leads – Michael Laposata, MD, PhD and Marisa B. Marques, MD

Methods:

- Three clinical pathologists with expertise in coagulation created diagnostic laboratory test algorithms to guide evaluation of patients with a prolonged Partial Thromboplastin Time (PTT) and a normal Prothrombin Time (PT)
- The 6 algorithms addressed:
  - age (adult versus newborn)
  - patient location (inpatient or outpatient)
  - symptoms (none, bleeding or thrombosis)
  - timing of the abnormal PTT result (recent versus extended period of time)

Evaluation of a Prolonged PTT

Degrade heparin in sample and repeat PTT -
if the PTT normalizes, heparin is the cause

↓

PTT mixing study (50:50 mix of patient & normal plasma)

↙ PTT Normalizes

↓

Factor deficiency- measure factors VIII, IX, XI, and XII

↘ PTT remains prolonged

↓

Inhibitor, most often a Lupus anti-coagulant; may be a Factor VIII inhibitor if PTT mixing study first normalizes and then becomes prolonged

Perform tests for specific inhibitor suggested by results of PTT mixing study

Diagnostic Algorithms

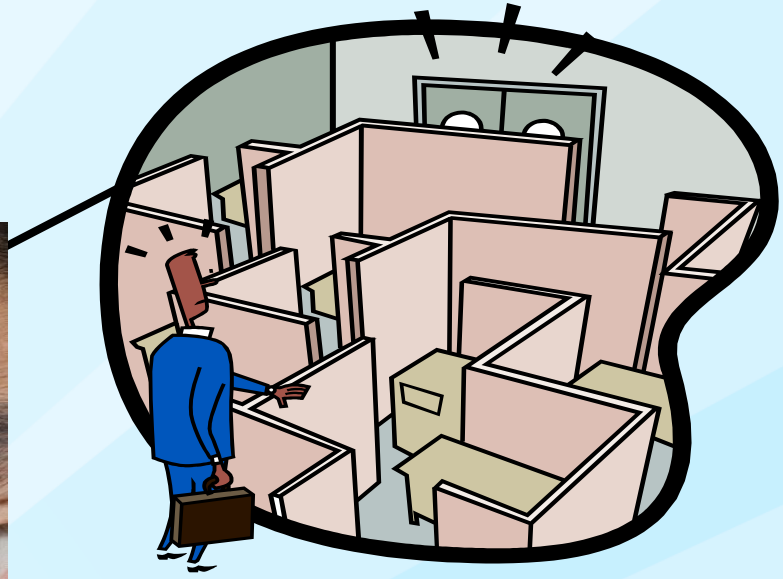
Project Leads – Michael Laposata, MD, PhD and Marisa B. Marques, MD

Status:

- Finalizing the paper to submit to peer reviewed journal

Next Steps:

- Implement the algorithms in other institutions for validation and improvement



Nomenclature

Project Leads – Elissa Passiment, EdM and Jim Meisel, MD, FACP

Goal:

- Demonstrate the complexity of test selection
  - Multiplicity - Hepatitis B surface antibody
    - HBs Antibody, Hepatitis Bs Ab, HBG, Anti-HBs
  - Complexity - rheumatoid factor- not for rheumatoid arthritis

Methods:

- Develop flow chart and tables demonstrating:
  - Complexity – Vitamin D
  - Breadth – Commonly ordered tests
  - Depth – Coagulation

Methods, cont.

- Test name variation based on:
  - Disease association
  - Methods used to perform the test
  - Name of developer
  - Inappropriate names (i.e. no link between name and what is being tested)
- Multiple test name abbreviations
  - Many evolved from implementing Laboratory Information Systems

Nomenclature Options for Vitamin D

Vitamin D2
Vitamin D3
25-0H vitamin D2
25-0H vitamin D3
25-0H vitamin D
25 hydroxy vitamin D2
25 hydroxy vitamin D3
25 hydroxy vitamin D
1,25 (OH)2 vitamin D2
1,25 (OH)2 vitamin D3
1,25 (OH)2 vitamin D
1,25 dihydroxy vitamin D2
1,25 dihydroxy vitamin D3
1,25 dihydroxy vitamin D
Vitamin D 25 Hydroxy D2
Vitamin D 25 Hydroxy D3
Vitamin D 1,25 Dihydroxy
Cholecalciferol
Ergosterol

CLIHC™ Nomenclature Team, 2011

Nomenclature Options for Commonly Ordered Tests

Key Name	Synonyms/Confounders	Abbreviation(s)
Alkaline Phosphatase	Alkaline Phos blood Alkaline phosphomonoesterase Alkaline phosphohydrolase Alkaline phenyl phosphatase	ALP,Alk Phos, AP, AKP
Beta HCG	BHCG (serum qualitative) Beta-Chorionic Gonadotropin Blood vs urine	BHCG, HCGB, Beta-HCG
Complete blood count with differential	Hematology profile; blood count; hemogram CBC with diff CBC with differential CBC with differential and platelets CBC w/diff & PLT CBC diff plts	 CBC CBC d/p

CLIHC™ Nomenclature Team, 2011

Nomenclature Options for Coagulation Tests

Anticardiolipin antibody	Anti-cardiolipin antibody Antiphospholipid antibody Anti-phospholid antibody	ACA ACL APA APL
Factor XII activity assay	Factor XII assay Factor XII functional assay Hageman Factor assay	 FXII
Lupus anticoagulant assay	Lupus anticoagulant Lupus antibody Anti-phospholipid antibody Lupus inhibitor Dilute Russell viper venom time Tissue thromboplastin inhibitor Dilute prothrombin time Kaolin clotting time Non-specific inhibitor	LA LAC LI APL DRVVT dRVVT TTI KCT DPT

CLIHC™ Nomenclature Team, 2011

Nomenclature

Project Leads – Elissa Passiment, EdM and Jim Meisel, MD, FACP

Status:

- Finalizing the paper to submit to peer reviewed journal

Next Steps:

- Investigate IT strategies and systems to assist the clinician in selecting the correct test - search support technology

There is substantial regional variability in test ordering practices that cannot be explained by case mix

Song, Y. et al. (2010). Regional Variations in Diagnostic Practices.
New England Journal of Medicine
www.nejm.org May 12, 2010
10.1056/nejmsa0910881 *nejm.org*

Clinicians' Challenges in Test Ordering and Interpretation of Test Results

Project Lead – John Hickner, MD, MSc

Goal:

- Raise awareness of the challenges clinicians face in test ordering and result interpretation

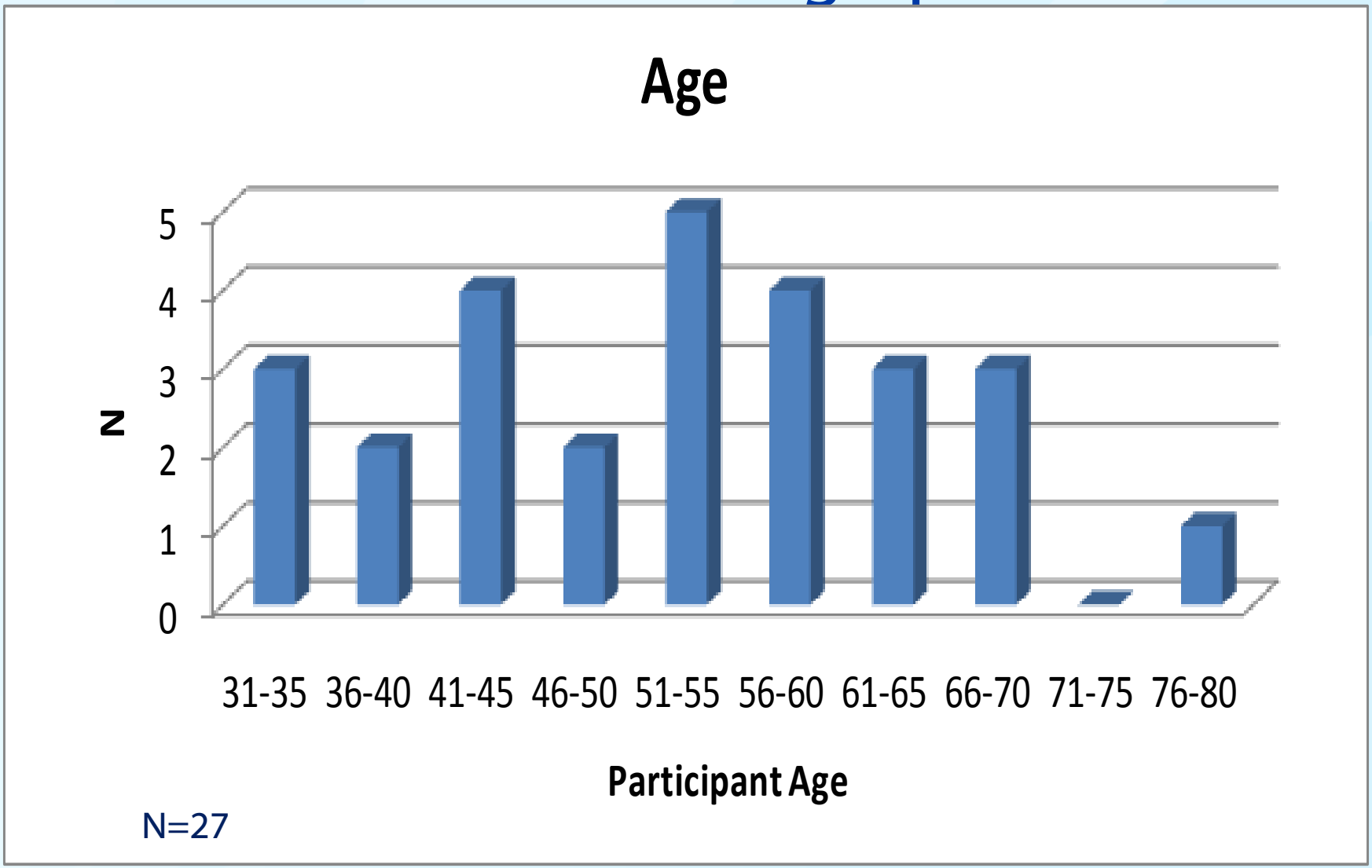
Methods:

- Phase 1 - Conduct three focus groups targeting internal, family, and general medicine practitioners
- Phase 2 - Using information from focus groups in Phase 1, conduct a national survey of clinicians

Focus Group Methods

- Sample frame
  - Family Practice & Internal Medicine Practitioners
  - Mailing lists of local clinicians from several insurance companies databases
- Sites
  - Pilot test at Cleveland Clinic, Cleveland, OH
  - March 17, 2010, Atlanta, GA
  - April 12, 2010, San Antonio, NM
  - May 20, 2010,Ann Arbor, MI

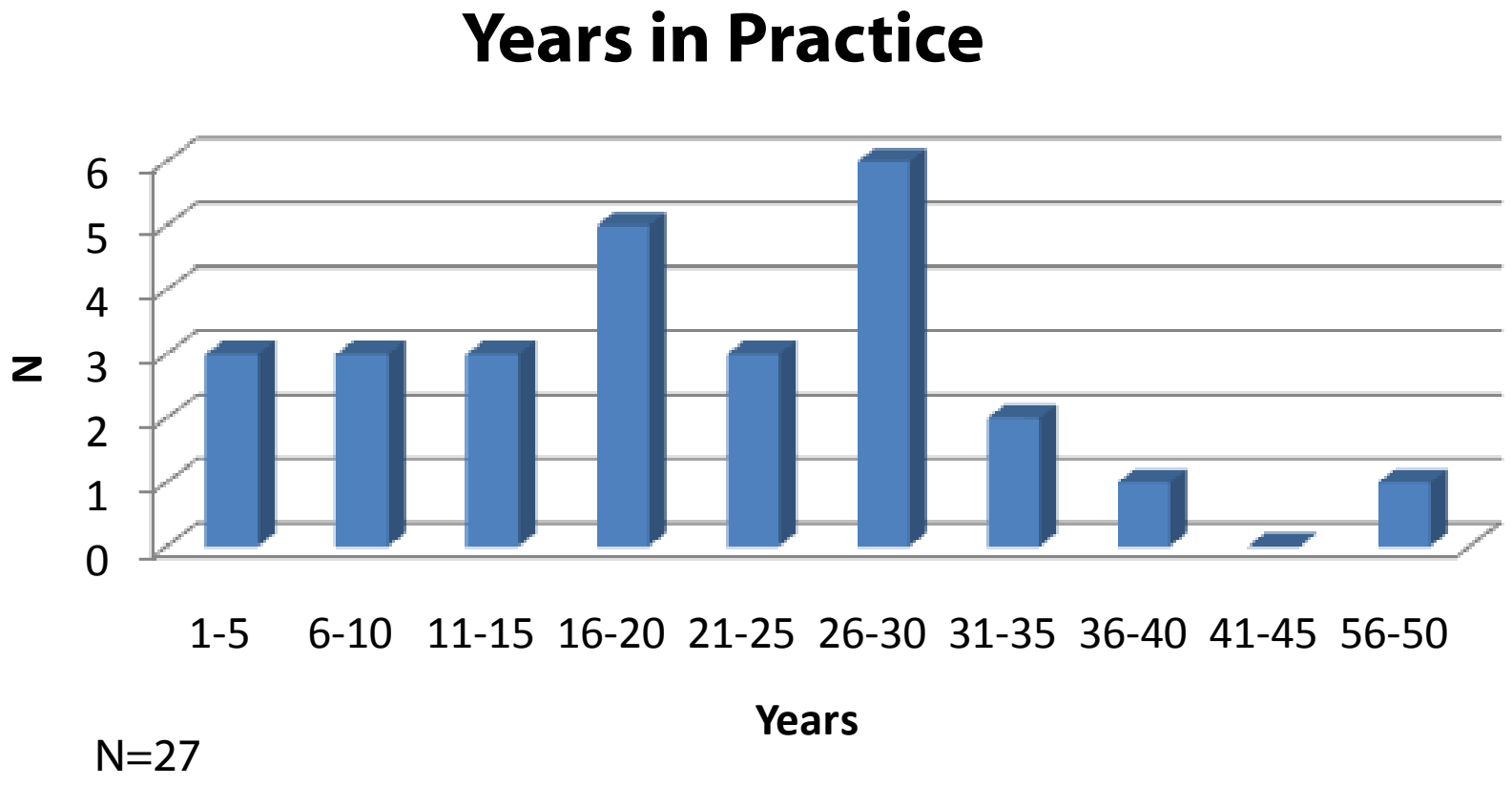
Clinician Demographics



N=27

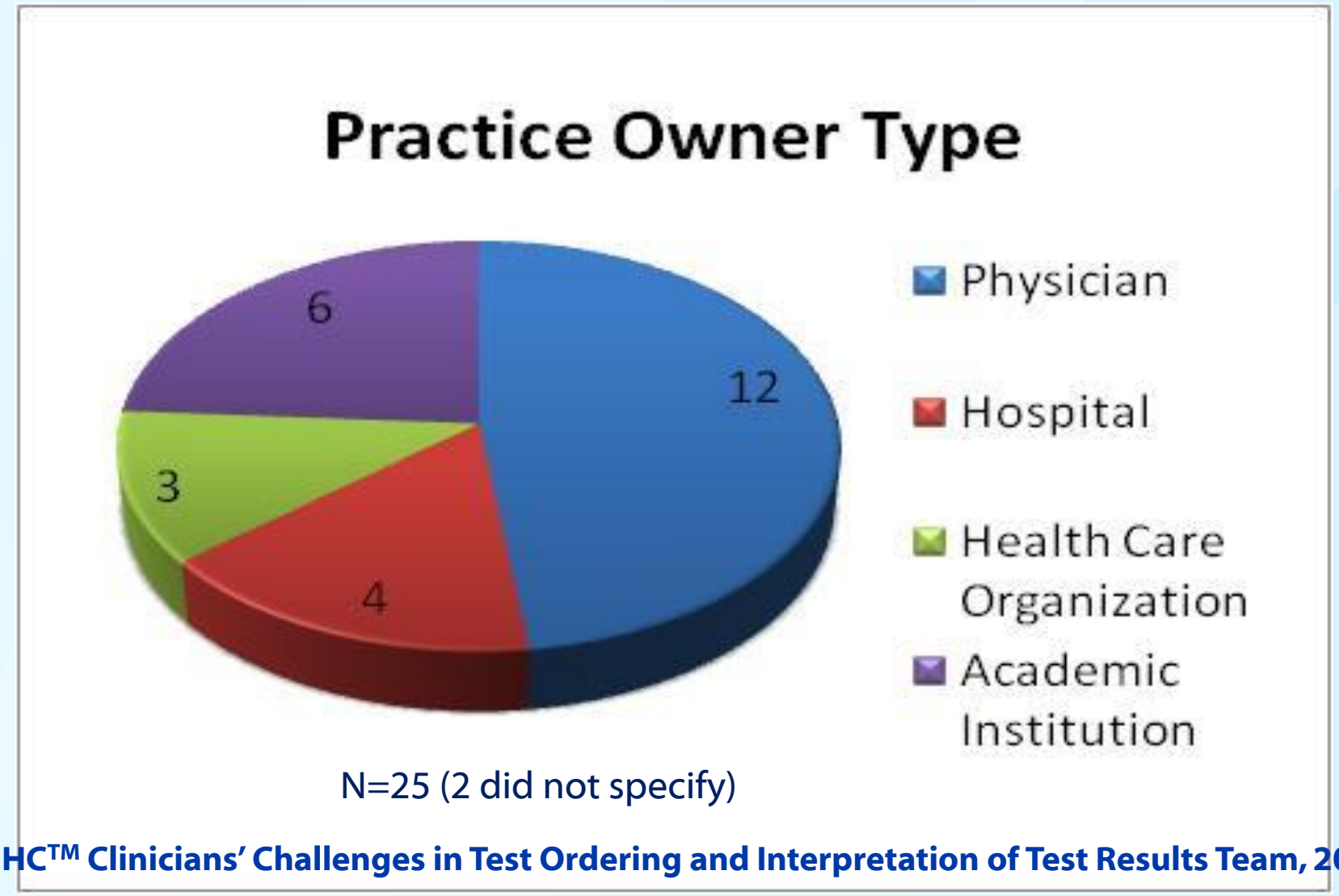
CLIHC™ Clinicians' Challenges in Test Ordering and Interpretation of Test Results Team, 2011

Clinician Demographics, cont.



CLIHC™ Clinicians' Challenges in Test Ordering and Interpretation of Test Results Team, 2011

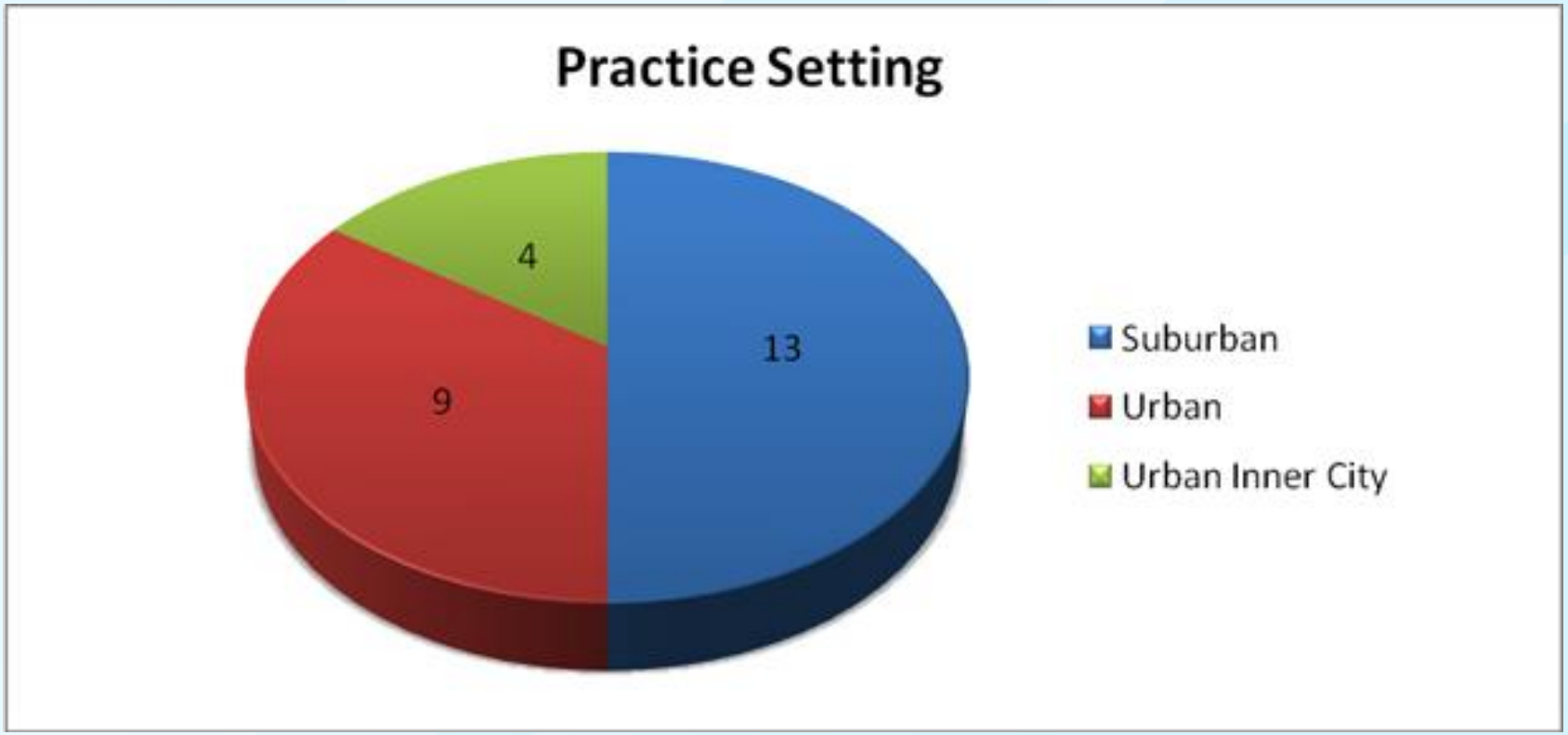
Clinician Demographics, cont.



N=25 (2 did not specify)

CLIHC™ Clinicians' Challenges in Test Ordering and Interpretation of Test Results Team, 2011

Clinician Demographics, cont.



N=26 (1 did not specify)

CLIHC™ Clinicians' Challenges in Test Ordering and Interpretation of Test Results Team, 2011

Challenges/ Barriers

Test Ordering

- Insurance and cost limitations
- Issues with accessing and communicating with laboratories
- Variations in test names
- Variable and nebulous practice guidelines

Enablers

Test Ordering

- Electronic resources
- Access to peers and colleagues
- Access and relationships with laboratory professionals
- Availability of practice guidelines

Challenges/ Barriers

Result Interpretation

- Insurance and cost limitations
- Varying practice guidelines and methodologies
- Difficulties in accessing and communicating with laboratory professionals
- Inconsistency of laboratory test results with clinical presentation
- Inadequate laboratory reporting and documentation

Enablers

Result Interpretation

- Access to electronic results and resources
- Access to peers and colleagues
- Access to laboratory professionals
- Follow-up testing information and reflex testing, when appropriate

Focus Group Summary

- Physicians are comfortable with selecting from a small working repertoire of common tests
- When results did not fit their suspected diagnosis, physicians relied on combination of patient presentation and own diagnostic instincts more than the laboratory results
- Laboratory consultation was a useful resource when the physician had effective and consistent access to laboratory services and were comfortable with laboratory professionals
- Electronic resources are becoming more important, with level of utilization dependent on ease of availability and a culture that encourages their use

Phase 2 - Clinicians' Survey

Methods:

- National sample of Family Practice and Internal Medicine physicians drawn from AMA Master File
- Target sample size of 1600
- Survey delivered via Web

Status:

- 60 Day Federal Register Notice submitted
- Survey developed
  - Cognitive testing completed
  - Expert review by national authorities
- Expect results – late Fall, 2011

Questionnaire Section Headings

- Ordering Uncertainty
- Ordering Influences
- Ordering Challenges
- Interpretation Uncertainty
- Interpretation Challenges
- Test Utilization Enablers
- Laboratory Consultation Practices
- New Test Awareness
- Diagnostic Evaluation Practices
- Demographic and Practice Characteristics

CLIHC™ Clinicians' Survey Team, 2011

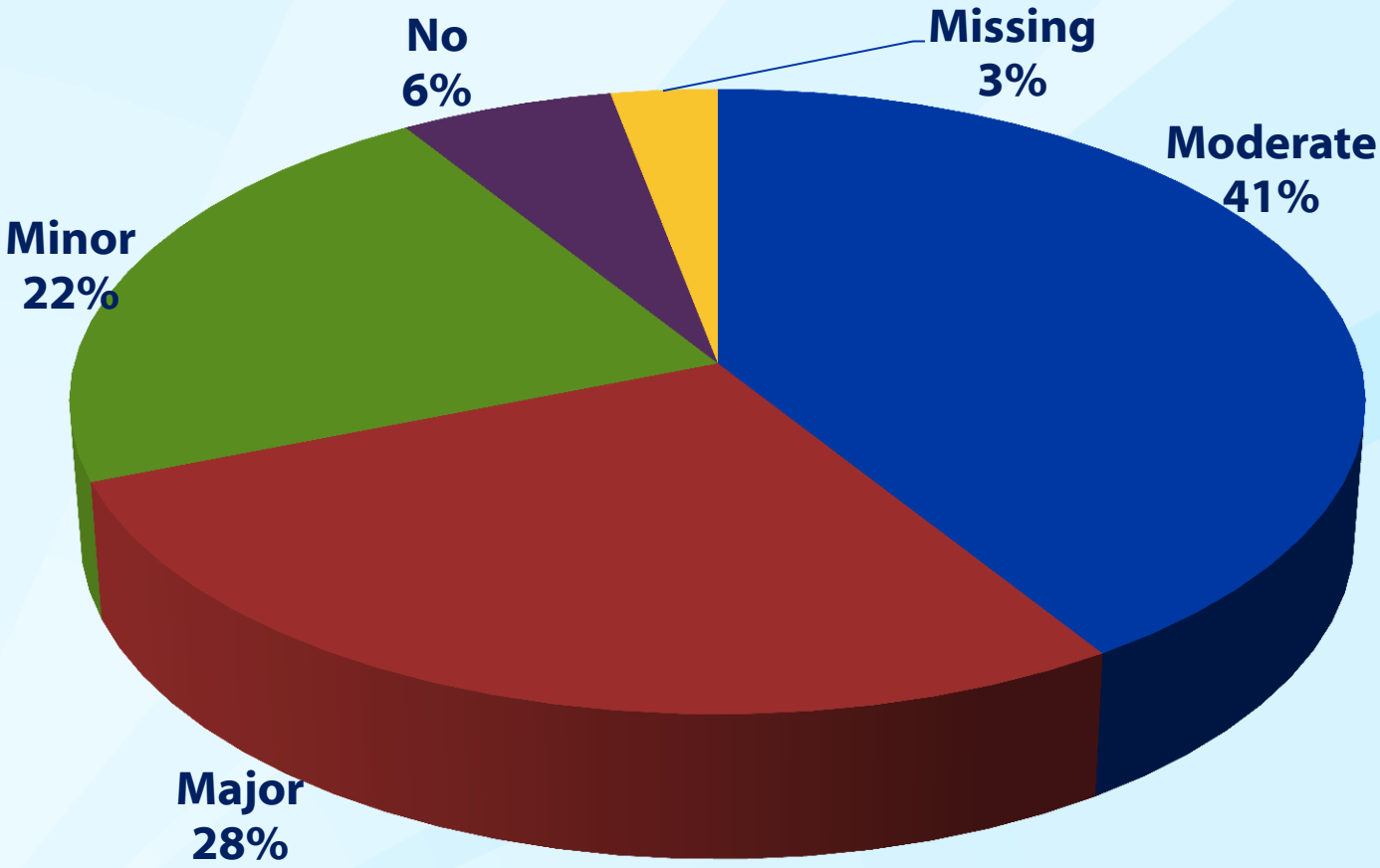
- **Q02. When uncertain what clinical laboratory tests to order for *diagnostic* (NOT for *screening* or *monitoring*) purposes, how often do you do the following?**

Please select one best answer for each of the below →	Daily	At least once per week	At least once per month	At least six times per year	At least once per year	Less than once per year	Never
Ask another primary care physician for advice	☐	☐	☐	☐	☐	☐	☐
Ask a laboratory professional (e.g., pathologist, laboratory technologist, etc.) for advice	☐	☐	☐	☐	☐	☐	☐
Refer the patient to a specialist	☐	☐	☐	☐	☐	☐	☐
Review electronic reference(s): professional articles, journals, newsletters	☐	☐	☐	☐	☐	☐	☐

CLIHC™

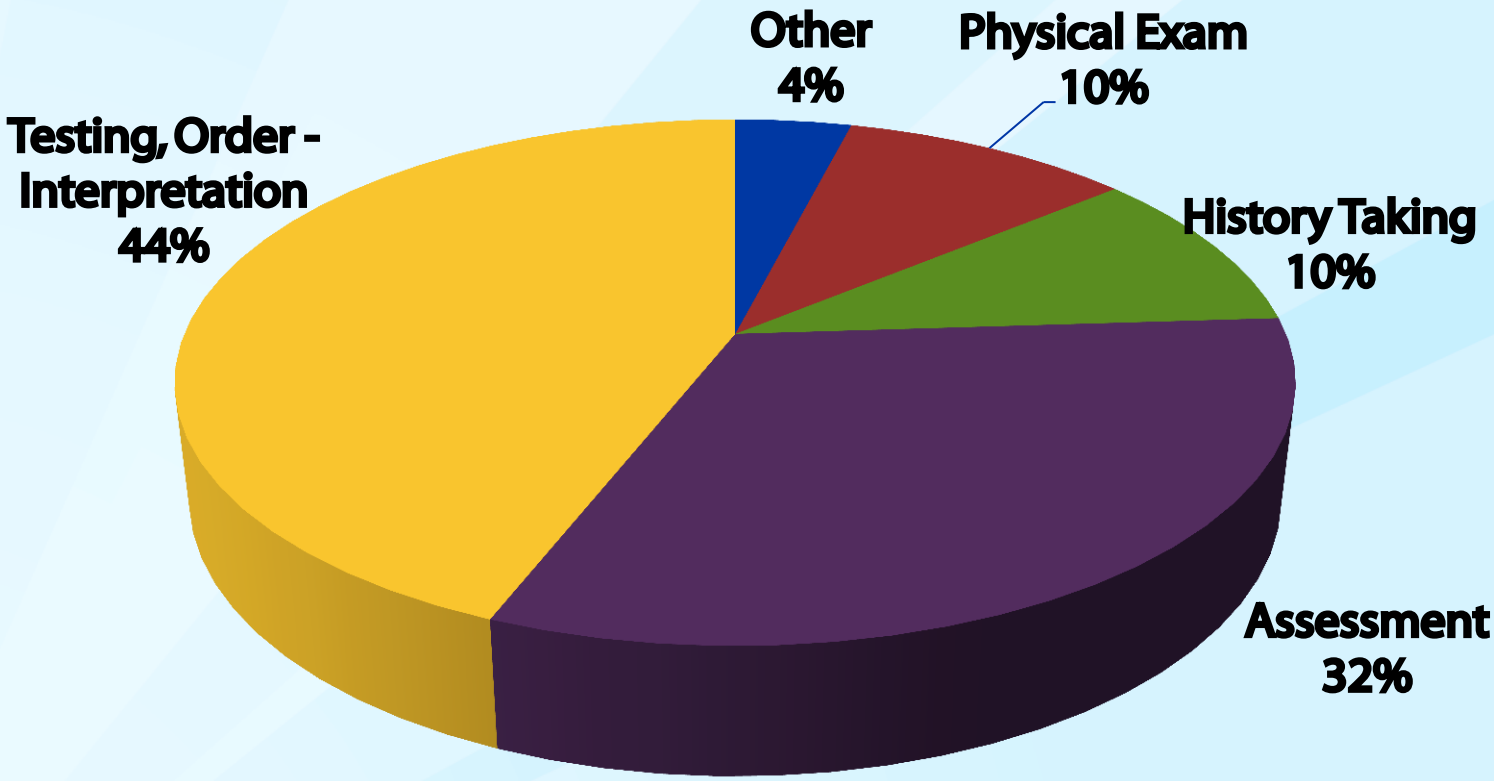
- Key Projects
  - Clinician Test Selection & Result Interpretation
    - Diagnostic Algorithms
    - Nomenclature
    - Survey of Clinicians' Challenges Education
    - **Improvement in Test Selection and Result Interpretation (ITSRI)**
  - Medical Student Education
    - Survey of US Medical Schools
    - Clinical Pathology Residency Education
  - Develop Organizational Collaborations

Severity of 583 Physician-Reported Diagnostic Errors



Schiff, G. D. et al. (2009). Diagnostic error in medicine: analysis of 583 physician-reported errors. *Archives of internal medicine*, *169*(20)

Frequency of 583 Physician-Reported Diagnostic Errors



Schiff, G. D. et al. (2009). Diagnostic error in medicine: analysis of 583 physician-reported errors. *Archives of internal medicine, 169*(20)

Interventions that Reduce Test Order and Result Interpretation Errors

- Guideline/ clinical pathways
  - National and locally developed
  - With or without electronic decision support
- Structured requisitions
- Reflex testing
- Consultations
- Interpretive comments

Published studies summarized by Paul Epner, Diagnostic Errors in Medicine, October 25, 2010

What we don't know

- What is the prevalence of diagnostic errors impacted by the testing process?
  - Failure to order necessary tests
  - Ordering of unnecessary tests
  - Inappropriate utilization of test results
- What are effective interventions that reduce diagnostic errors and could be initiated by laboratory professionals?
  - What settings are appropriate for these interventions?
  - What limitations exist in the use of these interventions?
  - What new sources of errors are created by the interventions?

Paul Epner, Diagnostic Errors in Medicine, October 25, 2010

Improvements in Clinicians' Test Selection and Result Interpretation (ITSRI)

Lead – Paul Epner, MEd, MBA

Goal:

- Demonstrate the effect of improvements in laboratory test selection and result interpretation on diagnostic errors

Methods:

- Develop methods to measure the effect of laboratory test selection and result interpretation on diagnostic errors
- Conduct pilot studies to determine the effect of improvements in laboratory test selection and result interpretation on diagnostic errors

Vanderbilt University Medical Center
Unpublished Study*

- Reviewed one week of consultation requests
- 53 cases total
  - 29 cases had appropriate test orders (55%)
  - 19 cases had incomplete test orders (36%)
  - 5 cases had inappropriate test orders (9%)
- Of 24 cases where tests were added or deleted following consultation, the diagnosis was impacted in 2 cases.
- The timing of the diagnosis in the other cases was not impacted only because of the near real-time addition of tests.

*Information and analysis provided by Jennifer M. Giltnane, MD, PhD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center

Next Steps

- Continue pilot studies to develop measures
- Continue to identify pilot study partners and sites
- Fall strategic planning meeting
  - Review goals for project
  - Review pilot study data
  - Develop strategic plan

Medical Student Education

Laboratory Medicine Education in US Medical Schools

- Required courses in 57% (68/120) of schools
- Few schools report no training at all (2 -4%)
- An ad hoc committee of The Academy of Clinical Laboratory Physicians and Scientists
  - Proposed medical student laboratory medicine curriculum
  - Developed:
    - Goals and objectives for training
    - Guidelines for instructional methods
    - Examples of how outcomes can be assessed

Smith, Brian R, et. al.; Educating Medical Students in Laboratory Medicine A Proposed Curriculum; AJCP; 2010: 133: 533-542

Survey of U.S. Medical Schools

Project Leads –Brian Smith, MD and John Hickner, MD, MSc

Goal:

- Raise awareness to the gaps in US medical school curricula and laboratory medicine training

Methods:

- Survey all 133 allopathic and 26 osteopathic U.S medical schools
- Recruit one medical student (via AMSA) per school to help complete the survey

Survey of U.S. Medical Schools

Project Leads –Brian Smith, MD and John Hickner, MD, MSc

Sample Questions:

- Does your school periodically have a formal review of the overall laboratory medicine curriculum by a Laboratory Medicine / Pathology physician? *Yes/No*
- Is competency in Clinical Laboratory Medicine formally evaluated as a distinct curriculum component? *Yes/No*

Status:

- Expect survey results in Fall, 2011

CLIHC™ Medical Survey Team, 2011

Next Steps

Depending on results, consider:

- Establishing a national resource for instruction
  - Refine the ACLPS curriculum in conjunction with primary care and specialty physician-educators
- Establishing a national assessment that schools can use (e.g., an on-line examination)
- Extending the survey to other health professionals
  - Physician Assistants
  - Advanced Practice Registered Nurse

Clinical Pathology Residency Education

Project Leads – Robert Hoffman, MD, PhD &
Michael Laposata, MD, PhD

Goal:

- Establish the nature and amount of clinical consultation education provided to clinical pathology residents
- Raise awareness to the gaps in, and solutions to improve clinical pathology residency education

Method:

- Conduct observational study of academic institutions assessing clinical pathology resident training activities

Clinical Pathology Residency Education

Project Leads – Robert Hoffman, MD, PhD &
Michael Laposata, MD, PhD

Results:

- 14 Accredited programs contacted – invited to visit 3
- "You would be surprised to see how little consultation there is"
- Some training programs have focal areas of consult activity
- Many programs not prepared to develop meaningful consultative roles for residents in laboratory medicine
- Obstacle- Limited # of doctoral level laboratory directors to teach residents

Next Steps:

- Obtain more data to substantiate the results
- Identify model programs to share nationally

Developing Organizational Collaborations

Project Lead – Scott Endsley, MD

Goal:

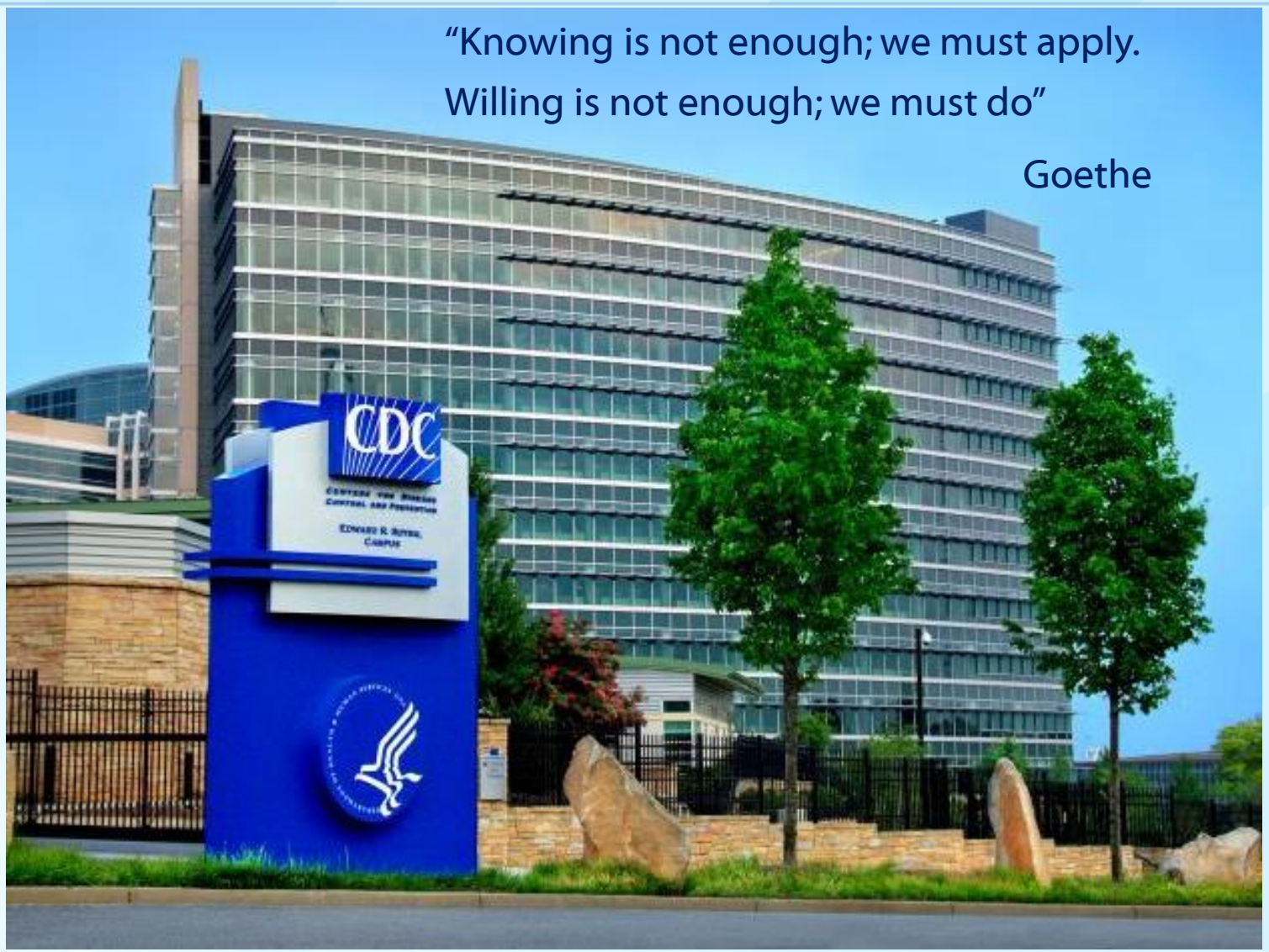
- Develop partnerships and collaborations that support and sustain CLIHC™ initiatives

Methods:

- Utilize a webinar to:
  - Increase the awareness of CLIHC™ work among key stakeholders
  - Solicit partnerships for current and future projects

Next Steps:

- Expand list of CLIHC™ collaborators
- Plan webinar for fall



For more information please contact:
Julie Taylor at Jtaylor1@cdc.gov

Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy, and Practice Program Office